REMARKS

In the Office Action, claims 22-37 are rejected under 35 U.S.C. §112, first paragraph. Applicant believes that this rejection should be withdrawn at least based on the reasons set forth below.

More specifically, the Patent Office alleges that claims 22-37 are not enabling pursuant to §112, first paragraph. Applicant believes that the specification provides sufficient support such that one skilled in the art can practice the subject matter as presently claimed without undue experimentation.

Of the pending claims at issue, claims 22, 27 and 35 are the sole independent claims. Claim 22 recites a method of modulating pupil dilation; claim 27 recites a method for optimizing pupil diameter in dim light by minimizing its dilation in response to less light; and claim 35 recites an ophthalmic, night vision formulation. Each of claims 22, 27 and 35 recite specific classes of alpha 1 antagonist compounds that are capable of disrupting endogenous compounds which simulate dilator muscles of the eye, such as an imidazoline and an alkylating agent.

As further supported in the specification on page 10, the claimed invention utilizes a specific class of compounds known as alpha 1 antagonists to inhibit pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Ophthalmic formulations that include such class of alpha 1 antagonist compounds can allow improvement in quality of vision in dim light without negative clinical effects in normal lighting conditions. See, Specification, page 10, lines 5-18. Examples of alpha 1 antagonists include an imidazoline, such as phentolamine, and an alkylating agent, such as phenoxybenzamine, as further supported in the Specification on page 11 at lines 7-12.

Further, Applicant has conducted experiments that demonstrate the beneficial effects of the claimed invention. For example, Table 1 on page 20 of the specification demonstrates that four different types of alpha 1 antagonist compounds can reduce pupil diameter in darkness in increased amounts as compared to dapiprazole. In this regard, a phentolamine-based solution reduced the pupil diameter by 3.5 mm; a phenoxybenzamine-based solution reduced the pupil diameter by 2.0 mm; a prazosin-based solution reduced the pupil diameter by 1.5 mm; and a tolamine-based solution reduced the pupil diameter by 1.5 mm. See, Specification, Table 1. In

Example 2, six additional specific types of alpha 1 antagonist compounds (e.g. tamsulosin, bunazosin, alfuzonsin, urapidil, ketanserin, and indoramin) are indicated to have some clinical effectiveness as well. See, Specification, page 19, line 28 to page 20, line 2.

Further, Applicants conducted an additional test to demonstrate the beneficial effects on vision by reducing the pupil diameter in dim light. As shown in Table 2, the glare and halo effects were reduced in addition to an improvement in depth perception by reducing the pupil diameter in dim light. See, Specification, page 21.

The Patent Office appeared to rely on page 4 of the specification in support of their position as indicated on page 3 of the Office Action. Contrary to this position, Applicants believe that the specification in this part provides further guidance to one skilled in the art, thus facilitating the practice of the claimed invention. With respect to reference of the indols, the specification provides that the alpha-2 activity as represented by indols is of no clinical benefit. As previously discussed, Applicants have discovered that compositions that display alpha-1 antagonist activity can improve quality of vision in dim light without negative clinical effect in normal lighting conditions. This is consistent with the testing that was conducted by Applicant and as illustrated, for example, in Table 1 on page 20 where the compound yohimbe having alpha-2 activity displayed no effect on pupil diameter reduction in dim light. Thus, this provides further guidance to one skilled in the art that the alpha 1 antagonist activity is most predominant with respect to reducing pupil size in dim light, and thus improving quality of vision.

With respect to specific types of alpha 1 antagonist compounds, such as an alkylating agent, these types of compounds may have less of an effect on pupil size as compared to, other types of alpha 1 compounds, such as an imidazoline, and further may cause greater redness. See, specification, for example, Table 1, page 20. Again, this should provide further guidance to one skilled in the art that one type of alpha 1 antagonist may be more preferred in formulation than another and also may require an additional compound to reduce eye redness. Clearly, this added description provides the skilled artisan with a greater frame work and understanding of the claimed invention, and thus facilitates the practice of same. Again, Applicant has indicated that at least 10 specific types of compounds having alpha 1 antagonist properties can display clinical effectiveness with respect to pupil diameter reduction in darkness (see, Specification, Table 1 and Example 2 at pages 19 and 20) and further that reduced pupil size does indeed have a

beneficial effect on vision in dim light (see, Specification, Table 2 at page 21) as previously discussed.

Based on at least these reasons, Applicant believes that the specification provides sufficient support and guidance such that one skilled in the art can readily practice the claimed invention with undue experimentation. Therefore, Applicant believes that pending claims 22-37 satisfy the enablement requirement pursuant to 35 U.S.C. § 112, first paragraph. Moreover, Applicants have presented new claim 52 as provided above and further respectfully submit that this claim satisfies 35 U.S.C. § 112 at least for substantially the same reasons as discussed above.

Accordingly, Applicant respectively requests that this rejection be withdrawn.

In the Office Action, claim 24 has been rejected as allegedly indefinite. Applicant has amended claim 24 in response to this rejection and further believes that this rejection should be overcome in view of same. This amendment was for clarifying purposes and further not intended to narrow and/or disclaim any claimed subject matter in view of same. Therefore, Applicant respectively requests that the rejection of claim 24 under 35 U.S.C. §112, second paragraph, be withdrawn.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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